

**No. 31015/67/2017-Pricing  
GOVERNMENT OF INDIA  
MINISTRY OF CHEMICALS & FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS**

A Wing, Shastri Bhawan,  
New Delhi 110 001

**Subject: Review application of M/s RPG Life Sciences Limited against price fixation of their formulation "Spironolacton 50 mg tablet" vide NPPA order No. S.O. 1687(E), dated 24.05.2017 issued under Drugs (Prices Control) Order, 2013 (DPCO 2013).**

**Ref: 1) Review application, dated 10.06.2017  
2) NPPA notification under review S.O. No.1687(E), dated 24.05.2017  
3) Record Note of discussions held in the personal hearing on 10.10.2017.**

1. This is a petition under paragraph 31 of the Drugs (Prices Control) Order, 2013 (hereinafter called the DPCO) filed by M/s RPG Life Sciences Limited (hereinafter called the petitioner) against notification S.O. No.1687(E), dated 24.05.2017 issued by the National Pharmaceutical Pricing Authority (hereinafter called the NPPA) fixing the ceiling price of their formulations Spironolacton 50 mg tablet.

2. The petitioner has contended as under:

I. NPPA has erred by considering the price as applicable Since August, 2014 instead of August, 2015 in their working sheet for calculation of Ceiling Price under Para 4 of DPCO, 2013.

II. AND WHEREAS, Company's formulation was scheduled under DPCO, 1995, and continues to be scheduled under DPCO, 2013 (both NLEM, 2011 and NLEM, 2015).

III. Despite company's product ALDACTONE 50mg is having more than 99% market share, the said formulation continues to be exempted from calculation under Para 6 as it was scheduled under DPCO, 1995.

IV. Under the circumstances:-

a. NPPA should consider Price to Retailer of INR 51.53 as applicable in August, 2015.

b. NPPA should allow for Ceiling Price to be continued to be calculated as per Para 16 to ensure swift correction in Ceiling Price.

c. As Company continues to hold more than 99% share, company requested this Department to please consider and calculate Non Applicability of Para 4 and Para 6 in this instance case.

5. In view of above, company prayed as under:

- a. To consider and conclude that NPPA had erred in pricing of Spironolactone 50mg Tablet under Sr. No. 5 of S.O 1687 (E) dated 24<sup>th</sup> May, 2017.
- b. To consider and conclude that NPPA must revised the ceiling price of Spironolactone 50mg in line with WPI increase as per Para 16 from SO 644(E) within 15 days.
- c. Pass a speaking order in respect hereof.
- d. Any other order in interest of this manufacturer.

3. **Comments of NPPA:**

I. Ceiling price of **Spironolactone 50mg Tablet** was notified as Rs. 3.60/tablet vide S.O. 1687(E) dated 24.05.2017 and revised to Rs. 3.45/tablet vide S.O. 2058(E) dated 30.06.2017 as per para 4, 6, 10, 11, 14, 16, 17, & 18 of DPCO, 2013.

II. The company has stated that correct methodology was not followed in arriving at the ceiling price of **Spironolactone 50mg Tablet**. The points raised by the company are not relevant. Price fixation has been done strictly in accordance with the provisions of DPCO, 2013. Details are as follows:-

Sl. No.	Company's Grievances	NPPA's comments
1.	Company has stated that NPPA has erred in considering the price as applicable in the month of August 2014 instead of August, 2015. Company has pointed out that PTR for their product was Rs. 51.53.	NPPA <u>considered the data provided by AIOCD-AWACS for month of August 2015 for fixing the ceiling price of <b>Spironolactone 50mg Tablet</b></u> . NPPA uploaded draft-working sheet of proposed ceiling price of this formulation also on its website. This was on the website of NPPA for 10 clear working days. M/s RPG Life Sciences Limited did not make any representation against the proposed retail price uploaded on NPPA's website.
2.	Company has stated that their formulation was scheduled under DPCO, 1995 and continues to be scheduled under DPCO, 2013 (both NLEM 2011 And NLEM 2015). Their product have more than 99.5% market share, therefore, the same to be exempted from calculation under para 6 of DPCO.	After notification of NLEM, 2015 on 10 <sup>th</sup> March 2016, NPPA has fixed the ceiling price based on para 18 of DPCO, 2013. Since the product is scheduled in DPCO, 1995, the price has been fixed taking into consideration para 6(2) of DPCO, 2013.

III. Company has not challenged any notification in respect of **Spironolactone 50mg Tablet** of **M/s RPG Life Sciences Limited** in the Court.

4. During the personal hearing, the company further stated that –

- 1) The aforesaid formulation was non-scheduled under NLEM, 2011 and subsequently under DPCO 2013 till 10<sup>th</sup> March, 2017.
- 2) Under Para 20 of DPCO 2013, the company increased the MRP of the formulation in August 2015 and provided both label claim of the pack and various invoices to different distributors with the MRP of Rs. 66.95.
- 3) The company also presented a certificate from AWACS-AIOCD which clearly stated that batch manufactured in August 2015 was available in the market at an MRP of Rs. 66.95 however, the data for August 2015 considered the relevant price for stock available in the market which was at Rs. 60.95.

It is proved beyond doubt that the company had implemented a price increase under Para 20 of DPCO 2013 to Rs. 66.95 from August 2015 but NPPA has not considered the same and must be directed to allow for the price increase.

Further, the company representatives argued that since the company holds more than 99% market share and was following retail price as set by NPPA under DPCO 1995, a non-reduction in price is valid based on Para 6(2) of DPCO 2013. Thus, NPPA must permit the company to sell at the same rate as August 2015 and only permit a change in WPI for calendar year 2015 and 2016 as per Para 16 of DPCO 2013.

4.2 NPPA representative stated that they have no further comments in addition to as stated above.

## **5. Examination:**

In the instant case, the company's contention is that NPPA has taken into account wrong and incorrect PTR of their product. The company stated that the actual PTR of their product Aldactone 50mg tablet, containing Spironolactone, was Rs.51.53 for a pack size of 15 tablets for the month of August, 2015. NPPA has considered the PTR of Rs.46.92 for pack size of 15 tablets, which according to company, is the PTR of August, 2014. The company has submitted necessary supporting documents in support of its claim of actual PTR of their product. In view of the above, NPPA may be directed to examine the documentary proof submitted by the company about the actual PTRs of their formulation Aldactone 50mg Tablet/15's pack and, after verification, re-fix/revise the ceiling prices of Spironolacton 50mg tablet, on merit.

5.2 The Company in its review application stated that their product was scheduled in DPCO, 1995 and continues to be scheduled under DPCO, 2013 (both NLEM, 2011 and NLEM, 2015), and, therefore, should be exempted from calculation under para 6 of DPCO, 2013. However, it is observed that the product of the company was scheduled drug in DPCO, 1995. The DPCO, 1995 was revised on 15.5.2013 and DPCO, 2013 came into force. This formulation was not appearing in Schedule I (i.e. NLEM, 2011) of DPCO, 2013. After the announcement of NLEM, 2015 in March, 2016, the Schedule-I of DPCO, 2013 was revised. This drug was included in the list of schedule I of DPCO 2013. Subsequently, NPPA fixed the ceiling price of the product under para 18 of DPCO, 2013. Therefore, the method adopted by NPPA for calculating the ceiling price of the product under para 6(2) of DPCO, 2013 is in order.

**6. Government Decision:**

**“NPPA is hereby directed to examine the documentary proof submitted by the company about the actual PTR of their formulation Aldactone 50mg Tablet, and after verification, re-fix/revise the ceiling prices of Spironolacton 50mg tablet, on merit.”**

**“The request of company for exemption from calculation under para 6 of DPCO, 2013 cannot be agreed to as the product was not included in Schedule-I (i.e. NLEM, 2011) of DPCO, 2013, and became non-scheduled formulation. The product has been included in the Schedule I (i.e. NLEM 2015) and the ceiling price of the product was fixed by NPPA after the revision of Schedule-I of DPCO, 2013. Therefore, the method adopted by NPPA for calculating the ceiling price of the product under para 6(2) of DPCO, 2013 is in order.”**

Issued on this date of 10<sup>th</sup> day of January, 2018.

**(M.K. Bhardwaj)**  
**Deputy Secretary**  
**For and on behalf of the President of India**

**To**

- 1. M/s. RPG Life Sciences Limited,  
RPG House, 463, Dr. Annie Besant Road,  
Worli,  
Mumbai-400 030.**
- 2. The Member Secretary,  
National Pharmaceutical Pricing Authority,  
YMCA Cultural Centre Building, New Delhi-110001**

**Copy to :**

- 1. PS to Hon'ble Minister (C&F), Shastri Bhawan, New Delhi for information.**
- 2. PSO to Secretary (Pharma), Shastri Bhawan, New Delhi for information.**
- 3. T.D., NIC for uploading the order on Department's Website**